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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,797	MUNN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008 and 03 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-13 and 30-39* is/are pending in the application.

4a) Of the above claim(s) *5-7,10,12 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9,11,13 and 30-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/14/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 4/14/2008, are acknowledged and entered. Claim 3 has been cancelled by Applicant. Claims 1-2, 4-7, 9-13, and 30-39 are pending and under examination. Claims 5-7, 10, 12, and 35-39 remain withdrawn from consideration.

Applicant's "considerable concern" over the alleged piecemeal prosecution of the present application is noted. Regrettably, a new ground of rejection under 35 U.S.C. 102(e) is being applied against the pending claims upon further consideration of the scope of the claims and the priority date afforded the prior art reference WO 2004/093871. Accordingly, this Office Action is **Non-Final**.

Supplemental Amendment

The supplemental reply filed on 7/3/2008 was not entered because supplemental replies are not entered as a matter of right except as provided in 37 CFR 1.111(a)(2)(ii). In the instant case, Applicant's reply filed 7/3/2008 only adds new claims 40-63, but does not (i) cancel a claim; (ii) adopt examiner's suggestions; (iii) place the application in a condition for allowance; (iv) reply to an Office requirement made after the first reply was filed; (v) correct informalities; or (vi) simplify issues for appeal. See MPEP 714.03(a). Applicant is invited to resubmit new claims 40-63 in reply to the present Office Action.

Response to Arguments

Any previous rejections and/or objections to claim 3 are withdrawn as being moot in light of Applicant's cancellation of the claim in the amendment filed 4/14/2008.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 4/14/2008. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Claim Rejections - 35 USC § 102 – New Ground of Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, 9, 11, 13, and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by **Prendergast *et al.*** (WO 2004/093871 A1; Published November 4, 2004) (prior art of record).

Prendergast *et al.* qualifies as prior art under 102(e)(2). The instant application claims priority to U.S. Provisional Application No. 60/459,489, filed April 1, 2003. Prendergast *et al.* is an international application designating the United States, was published under Article 21(2) in the English language, and claims priority to U.S. Provisional Application No. 60/458,162, filed March 27, 2003. Accordingly, pursuant to MPEP 706.02(f)(1), the 102(e) date of the WIPO publication is the international filing date or an earlier filing date for which a benefit is properly sought, *i.e.*, March 27, 2003.

Prendergast *et al.* teach methods of treating cancer (Abstract; page 1, lines 15-17) comprising administering to a patient, concurrently or sequentially, a therapeutically effective amount of at least one indoleamine 2,3-dioxygenase (IDO) inhibitor and at least one chemotherapeutic agent (page 4, lines 23-29; page 9, lines 15-19). Such chemotherapeutic agents include the instantly elected cyclophosphamide (*id.* at line 33) as well as the chemotherapeutic agents recited in instant claim 4 (page 4, line 29 to page 5, line 4). Suitable IDO inhibitors include 1-methyl-tryptophan, β-(3-benzofuranyl)-alanine and β-[3-benzo(*b*)thienyl]-alanine as recited in claims 1, 11, and 32-34 (page 10, line 18 to page 11, line 21, especially page 10, lines 21-23). Cancers that may be treated by the methods of Prendergast *et al.* include those cancers as recited in claim 13, *e.g.*, melanoma, colon, pancreatic, breast, prostate, etc. (page 14, lines 3-15). Synergistic activity as suggested by the instant claims is

taught at page 17, lines 14-17, wherein the inventors teach that the combination of an IDO inhibitor with a chemotherapeutic agent act synergistically to suppress tumor growth.

The reference thus anticipates the claimed methods of "treating a subject with a cancer" (claims 1 and 33), "augmenting the rejection of tumor cells in a subject" (claim 32), and "reducing tumor size or slowing tumor growth in a subject" (claim 34) comprising "administering to the subject" an inhibitor of IDO and administering at least one additional therapeutic agent, wherein the additional therapeutic agent is a cytotoxic antineoplastic chemotherapeutic agent such as cyclophosphamide. Applicant's characterization of the effects of administering an IDO inhibitor and chemotherapeutic agent, *i.e.*, augmenting the rejection of tumor cells or reducing tumor size or slowing tumor growth, as recited in the instant claims do not distinguish the claimed methods from those taught in Prendergast et al. because the same compounds are being administered to the same patients.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Prendergast *et al.*** (WO 2004/093871 A1; Published November 4, 2004) as applied to claims 1-2, 4, 9, 11, 13, and 32-34, *supra*.

Prendergast *et al.* teach as applied to claims 1-2, 4, 9, 11, 13, and 32-34, *supra,* and such teachings are applied herein in their entirety. Claim 30 differs from Prendergast *et al.* in the addition of a cytokine to the treatment methods of Prendergast *et al.* and claim 31 recites that the cytokine is GM-CSF or flt3-ligand.

While Prendergast *et al.* do not explicitly teach a method of treating cancer comprising administering an inhibitor of IDO, a cytotoxic chemotherapeutic agent, and a cytokine to a subject having cancer, the inventors do separately teach methods of treating cancer comprising administering: 1) an IDO inhibitor and a chemotherapeutic agent (page 4, lines 23-29; page 9, lines 15-19) and 2) an immunomodulatory agent, other than an IDO inhibitor, and a chemotherapeutic agent (page 16, lines 23-30). Suitable immunomodulatory agents include cytokines such as GM-CSF (page 16, line 31 to page 17, line 10, especially page 17, line 6).

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the treatment methods of Prendergast *et al.* such that a method of treating cancer comprising administering an inhibitor of IDO, a chemotherapeutic agent, and an immunomodulatory agent is achieved. Prendergast *et al.* teach that a combination of an IDO inhibitor and a chemotherapeutic agent or a combination of an immunomodulatory agent, other than an IDO inhibitor, and a chemotherapeutic agent are both effective methods to treat cancers. As such, one of ordinary skill in the art at the time the invention was made would have been imbued with at least a reasonable expectation that a combination of an inhibitor of IDO, a chemotherapeutic agent, and an immunomodulatory agent would also be effective to treat cancer.

Claims 1-2, 4, 9, 11, 13, and 30-34 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **WO 00/66764** and **Tsung *et al.*** (The Journal of Immunology, 1998, vol. 160, pages 1369-1377) in view of **Pinedo *et al.*** (The Oncologist, 2000, vol. 5, pages 497-500).

The invention relates to the treatment of cancer in a subject (*e.g.*, claim 1), augmenting tumor cell rejection in a subject (*e.g.*, claim 32), or reducing tumor size or tumor growth in a subject (*e.g.*, claim 34) comprising administering 1-methyl-tryptophan and cyclophosphamide. The specification and claims state that such a combination will be synergistic (*i.e.*, the effect of the combination is greater than that of either agent alone).

WO '764 teaches methods for increasing T cell proliferation comprising administering a tryptophan-enhancing agent (Abstract). Suitable tryptophan-enhancing agents include inhibitors of indoleamine-2,3-dioxygenase (IDO) (page 1, lines 18-21). Preferred IDO inhibitors include 1-methyl-tryptophan, β-(3-benzofuranyl)-alanine and β-[3-benzo(*b*)thienyl]-alanine (page 2, lines 12-15 and page 6, line 30 to page , line 10) as recited in the instant claims. The reference further teaches methods of treating cancer comprising administering an inhibitor of indoleamine-2,3-dioxygenase so as to elicit a T-cell response (*i.e.*, increased T-cell-mediated cytolysis of cancer cells (page 3, lines 30-33; page 18, lines 4-19 and lines 25-29). Tumor cells are shown to express IDO constitutively (see Examples). As such, WO '764 teaches that inhibition of IDO should be used to increase a subject's immune response, leading to lysis of antigen presenting cells, such as cancer cells which present one or more cancer associated antigens (page 15, lines 12-14).

The IDO inhibitors can be administered as a component of an immune response modulation composition, *i.e.*, in combination with another therapeutic agent (page 16, lines 22-23). Additional therapeutic agents can include T cells, antigens (*e.g.*, peptides, proteins), nucleic acids encoding antigens (*id.* at lines 25-27). Cytokines, including GM-CSF (as recited in instant claims 30-31) and IL-12 are taught to be useful in the immune response modulation compositions (page 17, lines 11-18).

Cancers constitutively expressing IDO are taught to reduce the local concentration of tryptophan and disable T-cell-mediated immune response to the cancer (page 17, lines 26-29). As such, WO '764 teaches that administering a tryptophan enhancing agent (such as an IDO inhibitor) will result in an increase in T-cell-mediated cytolysis of the cancer cell (*id.* at lines 31-33). Leukemia, mastocytoma, melanoma, and renal cancer cells were found to constitutively express IDO (page 21, lines 25-27). Table 1 also demonstrates that other tumor cell lines, including colon, pancreatic, breast, lung, sarcoma, and ovarian as recited in claims 13 and 39, also constitutively express IDO.

WO '764 does not explicitly teach combining inhibitors of IDO with cytotoxic antineoplastic chemotherapy agents (*e.g.*, cyclophosphamide) as instantly claimed.

Tsung *et al.* teach that a combination of cytokine IL-12 and the cytotoxic agent cyclophosphamide completely eradicates murine MCA207 sarcomas that are refractory to

treatment with either IL-12 or cyclophosphamide alone, thus motivating combining these agents for treating sarcomas (Abstract; Table 1).

Pinedo *et al.* discuss biological concepts of prolonged neoadjuvant treatment plus GM-CSF in locally advanced tumors. In this regard, it is disclosed that in patients with locally advanced breast cancer, a dysfunction of dendritic cells leads to a general immunosuppressive state with depressed T-cell reactivity (page 498, right column). Chemotherapy is disclosed to reduce the production of tumor-derived immunosuppressive factors, enabling the initiation of tumor-specific cytotoxic T-cell responses (page 498, right column) as well as to induce tumor cell necrosis and apoptosis, both of which cause release of antigen (*id.*).

The instantly claimed methods would have been *prima facie* obvious to one of ordinary skill at the time the invention was made. In support of the obviousness of the instantly claimed methods of treating cancer, the Examiner makes the following findings of fact:

a) The prior art motivates the use of IDO inhibitors, including 1–methyl-tryptophan, for the treatment of cancers, especially those that constitutively express IDO. Administration of an IDO inhibitor to a cancer patient is suggested to increase a subject's immune response, leading to lysis of antigen presenting cells, such as cancer cells which present one or more cancer associated antigens (WO '764, page 15, lines 12-14);

b) It was known in the art that cyclophosphamide combined with IL-12 is more effective than either agent alone due to immunopotentiation of delayed-type hypersensitivity in sarcomas resulting from cyclophosphamide (Tsung *et al.*); and

c) It was known in the art that chemotherapy leads to a reduction in the production of tumor-derived immunosuppressive factors, enabling the initiation of tumor-specific cytotoxic T-cell responses as well as an induction of tumor cell necrosis and apoptosis, both of which cause release of antigen (Pinedo *et al.*).

In view of the above findings, the skilled artisan would have been imbued with at least a reasonable expectation that administration of 1-methyl-tryptophan and cyclophosphamide, optionally combined with a cytokine, would result in an effective treatment of cancer. As taught in WO '764, 1-methyl-tryptophan would be expected to increase a subject's immune response (*via* inhibition of IDO), leading to lysis of antigen presenting cells, such as cancer cells which

present one or more cancer associated antigens. Addition of a cytotoxic chemotherapeutic agent such as cyclophosphamide would be expected to reduce the production of tumor-derived immunosuppressive factors, enabling the initiation of tumor-specific cytotoxic T-cell responses as well as to induce tumor cell necrosis and apoptosis, both of which would cause release of antigens from tumor cells. Finally, the cytotoxic T-cell response initiated by cyclophosphamide would be further enhanced by the increased T-cell proliferation induced by inhibition of IDO by 1-methyl-tryptophan as taught in WO '764.

Applicant's arguments have been considered but are not persuasive. Firstly, it is noted that Applicant discloses at page 51, lines 5-6 that 1-MT is a lead compound in the "new class" of immunomodulatory agents, designed to block immunosuppression mediated by IDO. In other words, the present application discloses the same effect of 1-MT as WO '764. Applicant argues that a person of ordinary skill in the art "having common sense" at the time of the invention would not have reasonably considered combining the teachings of WO 00/66764, Tsung *et al.*, and Pinedo *et al.* to obtain the claimed invention. In support of this argument, Applicant submits that WO '764 teaches away from combining IDO inhibitors with cytotoxic chemotherapeutic agents. However, no where does Applicant specify where in WO '764 such teaching away occurs.

Applicant asserts that WO '764 teaches that T cells can be cultured *in vitro* with a tryptophan enhancing agent "for expansion and eventual return to the subject.., leading to lysis of antigen presenting cells, such as cancer cells" (page 15, lines 9-14) and further that WO 00/66764 teaches that cytokines that stimulate an immune response (such as IL-12 and GM-CSF) can also be used *in vitro*, along with tryptophan enhancing agents, to expand antigen responsive T cells *in vitro*, for subsequent administration of the expanded T cells into a patient for the treatment of cancer (page 17, lines 11-18 and page 16, lines 7-21). Applicant submits that such teachings of the *ex vivo* expansion of T cells with a tryptophan enhancing agent and optionally a cytokine provide no reason whatsoever to contemplate the administration an IDO inhibitor along with a cytotoxic antineoplastic chemotherapeutic agent to a subject for the treatment of cancer. However, contrary to Applicant's characterization of WO '764, the reference explicitly teaches and suggests administering an IDO inhibitor to treat cancer in a subject. For example, the inventors teach that T cell proliferation can be increased *in vitro* by administration of tryptophan

enhancing agents to T cell culture, or *in vivo* by administration of tryptophan enhancing agents (Abstract). Further, the inventors teach immune response modulation compositions (page 3, lines 17-20) and methods for treating cancer cells which have evaded or have the potential to evade T-cell mediated cytolysis comprising administering to a subject in need of such treatment an amount of a tryptophan enhancing agent effective to increase T-cell mediated cytolysis of the cancer cell (page 3, lines 30-33). The reference thus explicitly teaches administration of a compound of the invention to a subject having cancer, especially cancers that constitutively express indoleamine 2,3-dioxygenase (page 4, line 1). In fact, Examples 4 and 5 of WO '764 teach administration of 1-MT to mice bearing WEHI 3B tumors which constitutively express IDO.

With regard to Tsung *et al.*, Applicant argues that Tsung *et al.* is directed solely to the combination of cyclophosphamide and IL-12 and that Tsung *et al.* teaches away from "considering any modification whatsoever" of a method of treating cancer by the administration of IL-12 and cyclophosphamide. However, the Examiner respectfully submits that an artisan skilled in the art of oncology would reasonably expect that two known anticancer therapies could be combined to elicit a third anticancer therapy. This is especially true when one considers the teachings of WO '764, wherein the inventors teach that other agents which stimulate immune response can also be administered to the subject (page 17, lines 11-12), including cytokines such as IL-12 (id. at lines 14-15). Thus, when the teachings of Tsung *et al.* and WO '764 are taken together *in their entirety*, one skilled in the art would be motivated to administer cyclophosphamide and IL-12 (Tsung *et al.*) in combination with an IDO inhibitor such as 1-MT to treat a cancer expressing IDO (WO '764).

Applicant's statement that the Examiner asserts that cyclophosphamide is an immunopotentiating agent is incorrect. Cyclophosphamide, as taught by Tsung *et al.*, is an agent "known to potentiate the DTH [delayed-type hypersensitivity] response" (Abstract). The Examiner stated that the effect of cyclophosphamide when combined with IL-12 is "due to immunopotentiation of delayed-type hypersensitivity in sarcomas resulting from cyclophosphamide". The Examiner's characterization of the effect of cyclophosphamide is taken directly from the teachings of Tsung *et al.* (Abstract).

With regard to Applicant's argument that the results of Tsung *et al.* were not reproduced with other chemotherapeutic agents such as 5-FU, the Examiner reminds Applicant that other chemotherapeutic agents are not under examination at this point in prosecution because Applicant elected cyclophosphamide. As such, what Tsung *et al.* teaches or suggests with respect to other chemotherapeutic agents is not pertinent to the present rejection.

With regard to Pinedo *et al.*, Applicant appears to argue that that Pinedo *et al.* teach a "complicated, multi-step method" for treating cancer and that one skilled in the art would not combine this method with the method of WO '764 and/or Tsung *et al.* For example, Applicant argues that one of skill in the art would have no reason to remove a single component of the Pinedo *et al.* method, such as administration of cyclophosphamide, to combine with the administration of an inhibitor of IDO, as taught in WO '764. The Examiner questions, however, why one skilled in the art would have to remove a component of the Pinedo *et al.* method in order to combine this method with administration of an inhibitor of IDO? The "comprising" language of the instant claims allows for the administration of any number of therapeutic agents in combination with the explicitly recited IDO inhibitor and chemotherapy agent. As such, the only modification of the Pinedo *et al.* method required to meet the limitations of the claims is addition of an IDO inhibitor as taught in WO '764.

The state of the art in cancer chemotherapy is such that combining two known treatment methods to form third treatment method would have been *prima facie* obvious at the time the invention was made. The skilled artisan would have been imbued with at least a reasonable expectation that addition of an IDO inhibitor to the treatment method of Tsung *et al.* (cyclophosphamide + IL-12) and/or Pinedo *et al.* (doxorubicin + cyclophosphamide + GM-CSF) would lead to an effective treatment method for treating a subject having cancer as recited in the instant claims.

Applicant's results have been considered and are demonstrative of unexpected results over the cited prior art only for the treatment of melanoma with cyclophosphamide and 1-MT as evidenced by Figure 11B, but not for the broad scope of the claims which encompass the treatment of any cancer with any cytotoxic antineoplastic chemotherapy agent in combination with 1-methyl-tryptophan, β-(3-benzofuranyl)-alanine, β-(3-benzo(b)thienyl)-alanine, or 6-nitro-D-tryptophan.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Non-Provisional Application No. 10/780,150

Claims 1-4, 9, 11, 13, 30-31, and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-10 and 17-26 of copending Application No. 10/780,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the subject matter claimed in the '150 patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant requests that this rejection be held in abeyance until the indication of otherwise allowable subject matter. As no allowable subject matter have been indicated in this Office Action, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614